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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,615	06/01/2001	Mark A. Brudnak		2272

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03/05/2003

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 03/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,615

Applicant(s)

BRUDNAK, MARK A.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,9-11 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-8,12-15 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures

DETAILED ACTION

Claims 1-20 are presented for examination.

Election/Restrictions

Applicant's election of the species of composition comprising the ingredients galactose, acid fast protease, peptidase, cysteine protease and phytase, in Paper No. 9, filed January 6, 2003, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3, 4, 9-11 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species of compositions, there being no allowable generic or linking claim. As discussed above, election was made **without** traverse in Paper No. 9, filed January 6, 2003.

Claims 1, 2, 5-8, 12-15 and 17-20 have been examined on the merits to the extent they read on the elected invention. The composition comprising the ingredients galactose, acid fast protease, peptidase, cysteine protease and phytase is considered to be free of the prior art. The search and examination has

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been extended to additional species recited in the claims. See MPEP § 803.02.

Compliance with Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). See the amino acid sequences inserted in the preliminary amendment to page 4, line 25. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

While the sequences disclosed do not comply with the sequence rules cited above, the sequence is deemed non-essential to the examination of this application at this time because no sequence is recited in the claims. Applicant is therefore given the entire period for responding to this action to comply with the sequence rules. **FAILURE TO COMPLY FULLY WITH THE SEQUENCE RULES WITHIN THE RESPONSE PERIOD SET FOR THIS OFFICE ACTION WILL BE CONSIDERED AN INCOMPLETE RESPONSE.**

Note that the insertion at page 4, line 25, is also held in this action to be new matter. See below. Thus, if applicant

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removes the sequences encompassed by the Sequence Rules set forth in 37 CFR 1.821(a)(1) and (a)(2), applicant need not comply with the Sequence Rules.

Specification

The preliminary amendment filed December 4, 2001, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

- the insertion at page 4, line 25;
- the insertion at page 6, line 26;
- the insertion at page 7, line 2.

Applicant is required to cancel the new matter in the reply to this Office Action.

The disclosure is objected to because of the following informalities: the amino acid -- cysteine -- has been misspelled throughout the specification and claims as "cystein".

Appropriate correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5-8, 12-15 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "genomeceutical" renders the claims confusing, and therefore indefinite. The term does not have an art-accepted meaning. While it is noted that an applicant may be his or her own lexicographer, it is also noted that the meaning of terms appearing in the claims must be clear. While a definition of the claim appears in the first full paragraph at page 4, that definition is sufficiently broad to encompass any known substance. Thus, it is not clear what applicant seeks to include or exclude from the claims. Because the term "genomeceutical" fails to place the skilled artisan on notice of what is or is not encompassed by the claim, a holding of indefiniteness under § 112, second paragraph is required.

The term "physiologically effective amount" is indefinite because any amount of a claimed agent will have some

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physiological effect. Thus, it is confusing how the language is intended to limit the claim. Note that this ground of rejection would be withdrawn if the recitation were amended to recite -- a therapeutically effective amount --.

The recitation "of the type that affects expression of a DPPIV like compounds" [sic, compound], is indefinite. First, the criteria for determining whether a compound is "like" DPPIV are not clear. Moreover, the criteria for determining whether a substance is "like" another is entirely subjective. Thus, the metes and bounds of the quoted language are not clear in this regard.

Also, it is not clear whether the compound must actually affect expression of DPPIV like compounds, or if it merely may be "of the type" that affects this expression. Moreover, it is not clear what this "type" is. Thus, the language "of the type" is not clear because no criteria is provided for determining what the language means.

Further still, the claims are indefinite because of the recitations "phytase like" and "DPPIV like". Again, the criteria for determining whether a compound is "like" phytase or DPPIV are not clear. Moreover, the criteria for determining whether a substance is "like" another is entirely subjective.

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The recitation "acid fast protease" is indefinite because it is not clear what the recitation means. Specifically, it is not clear whether the recitation means that the enzyme is active at an acid pH, whether the enzyme is optimally active at an acidic pH, whether the enzyme can survive treatment at an acid pH, what enzyme activity must be retained after acid treatment, and what that acidic pH must be. It is noted that the definition on page 9 requires only a "high" acid stability and ability to function in the stomach to hydrolyze larger proteins into smaller peptides. However, because of the entirely relative nature of the term "high," it is not clear how high the stability must be, or what the stability criteria are.

Lastly, the recitation "compound" at line 10 of claim 17 is indefinite because the mixture of galactose and protease is not disclosed as reacting to create a new "compound" as the claim recites. Rather, the ingredients are mixed to produce a -- composition --. Changing the word "compound" to the word -- composition -- would overcome this ground of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 17, 19 and 20 are rejected under 35

U.S.C. 102(b) as being anticipated by Chantler et al (EP 0 372 702).

The cited claims recite a composition comprising galactose and a protease, and a method of preparing such a composition by mixing the ingredients together. Chantler discloses a composition comprising galactose and a protease, chymotrypsin, and a method of preparing that composition by mixing the ingredients together. See, e.g., page 5, lines 31-32, disclosing "a 0.1 M aqueous solution of D-galactose containing chymotrypsin, previously sterilized by passage through an ultrafilter." Note that in view of fact that chymotrypsin can withstand an acid pH, chymotrypsin is considered to be encompassed by the recitation "acid fast protease" appearing in the claims. A holding of anticipation over the cited claims is therefore required.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6-8, 12, 14, 15 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knap et al (U.S. Pat. 5,885,618).

The cited claims recite a plurality of compositions comprising galactose and/or protease and/or phytase. Knap discloses the preparation of compressible enzyme powders by combining carbohydrates with enzymes. See column 1, lines 43-55. Knap discloses that suitable carbohydrates include sugars, including galactose. See column 2, lines 17-24. Knap discloses that suitable enzymes include enzymes used as digestive aids, including proteases and phytases, and mixtures thereof. See column 2, lines 37-51.

Thus, although Knap does not disclose a single anticipatory embodiment reciting the claimed combination of galactose and enzymes, the cited claims are clearly obvious in view of Knap's

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disclosure of the desirability of combining the claimed ingredients. Note specifically that it is *prima facie* obvious to apply a known material to an art-recognized use of that material. See MPEP § 2144.07, citing, *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 335, 65 USPQ 297, 301 (1945) ("[r]eading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle."). Thus, because the cited claims do nothing more than select suitable combinations of stabilizers and enzymes from the list provided in the Knap, a holding of obviousness is clearly required.

No claims are allowed. However, claims directed to compositions comprising the ingredients galactose, acid fast protease, peptidase, cysteine protease and phytase are considered to be free of the prior art and would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner

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can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
March 4, 2003